The Power of AI to Transform Clinical Trials

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Artificial intelligence (AI) technology, combined with big data, hold the potential to solve many key clinical trial challenges.

These include increasing trial efficiency through better protocol design, patient enrolment and retention, and study start-up, which were each named as prime candidates for improvement by nearly 40 percent of sponsors in a recent ICON-Pharma Intelligence survey(1). With clinical trials accounting for 40 percent of pharma research budgets(2), sponsors need new ways to accelerate timelines and reduce costs.

Data-driven protocols and strategies powered by advanced AI algorithms processing data collected from mobile sensors and apps, electronic medical and administrative records, and other sources have the potential to reduce trial costs. They achieve this by improving data quality, increasing patient compliance & retention, and identifying treatment efficacy more efficiently and reliably than ever before.

As a result, fewer patients are needed to generate statistically significant study data, and fewer patients drop out. Adopting these novel innovations does present challenges, with developing analytics that generate actionable clinical insights from big data high among them.

Nonetheless, there exists significant potential for transforming trials, for example potentially uncovering routes to new therapeutic options in masses of data that may not be found by humans alone.

Improving Pharma R&D Efficiency

In our industry survey and whitepaper, 'Improving Pharma R&D Efficiency' when asked what technologies would have the most impact improving clinical trial efficiency, the top answer from survey respondents was leveraging big data and AI at 36 percent.

Advancing clinical trials

The AI transformation of clinical trials starts with protocol development, reducing or replacing outcome assessments that may be more responsive to change than traditional methods and utilising remote connected technologies that reduce the need for patients to travel long distances for sites visits. Relying on traditional site based outcome assessments can lead to less than optimal protocol design can slow enrolment and lead to poor patient retention, driving up trial costs or even dooming a programme.

Applying AI to big data has the potential to shape insights from masses of real-world data (RWD) into protocol designs. Objective data from devices and sensors captured in real time data from individuals as they go about their normal lives has the potential to capture more meaningful clinically relevant insights and be used to assess and develop trial objectives, endpoints and procedures.

In the past, researchers relied heavily on verbal or written evidence from patients at clinical visits and direct clinic observations to assess patient progress. This subjective evidence can be unreliable, prone to inter and intra rater variability and not provide enough information for analytics and decision making and while patient reported outcomes are a key component of any trial, the addition of objective data to add context to the subjective assessment particularly when machine learning and AI platforms can be used.

Gathering real-time, real-world patient data with wearable devices, on the other hand, can help produce consistent, objective evidence of actual disease states and impacts of drug efficacy on disease symptoms. Today there are a vast range of biometric signals that can be captured including heart rate, blood pressure and sleep and activity collected 24/7. It is much richer and more detailed than data collected in the clinic, and has the potential to be more responsive to change.

AI analysis of live remote data also can detect when patients may not be compliant, allowing clinical personnel to intervene before a patient's data must be excluded. Sponsors already recognise big data can help solve these kinds of problems - 28 percent of the ICON-Pharma Intelligence survey respondents reported that big data will help clinical trial operations.

Engaging patients and finding new insights

AI-enabled trial management systems can help keep patients engaged. Technologies such as digital reporting apps, as well as wearables, allow for real-time engagement and communication, and support patient-centric trials. Patients can send feedback on treatment symptoms and manage medication intake, and can share information with researchers, reducing or eliminating the need for patients to travel to sites, which increases patient adherence and compliance.

Moreover, reducing the frequency of clinical visits can lower site costs, and improve quality of patient experience on the trial (fewer and shorter clinic visits).

AI analysis of RWD-generated by mHealth technologies not only allows for the monitoring of objective high-quality data in real-time as patients live their lives, but also helps find clinically relevant signals among masses of data not possible using current analytic techniques. With advanced analytics, researchers can gain deeper insights into how a treatment affects symptom progression or quality of life. Moreover, expertise in machine learning can help to develop novel endpoints.

AI analysis of big data has the potential to generate new insights into disease processes that could open up new treatment avenues. It has the ability to advance the concept of personalised medicine by identifying patients most likely to respond to specific treatments based on their individual characteristics and responses to previous treatment.

This will reduce the risk of drug development by creating predictive models that are much more powerful, increasing chances that a given therapy will work in clinical trials. More importantly, it will bring more innovative products to patients sooner, transforming not only clinical trials, but also the health and lives of millions of patients as well.

References

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